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510K SUMMARY OF HEMAPROMPT GASTRIC for use in detection of gastric occult blood. K031356
This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

The HemaPrompt Gastric slide, used with a buffered developer and a buffered guaiac paper, is a guaiac based test for the detection of occult blood in gastric samples. The test is not affected by low pH, and is free from interferences by normal therapeutic concentrations of iron, ranitidine, and antacids. A separate area is provided to test for the pH of the specimen.

When a gastric specimen containing blood is applied to the HemaPrompt Gastric test paper, hemoglobin from the lysed blood cells in the sample comes in contact with the guaiac in the paper. The developer, a buffered solution of alcohol and hydrogen peroxide, which is applied with two drops to the reverse side of the guaiac on the slide, creates a peroxidase-like reaction in the presence of hemoglobin which in turn causes a blue coloration in the test paper. This test will turn blue in the presence of more than 100 mcg Hb/ ml gastric juice

As with any occult blood test, results with HemaPrompt Gastric cannot be considered conclusive evidence of the presence or absence of upper bowel bleeding or pathology and is designed for use as a preliminary screening aid and is not intended to replace other diagnostic procedures such as endoscopy or Xray procedures. Furthermore the pH cannot be used to indicate the specimen is of gastric origin.

EXPECTED AND PERFORMANCE RESULTS

The use of guaiac impregnated paper for the detection of occult blood and its significance in gastric contents has been less extensively studied than fecal occult blood. One study of 153 gastric aspirates from 50 intubated healthy adults indicated all aspirates with more than 50 micrograms of hemoglobin! ml were positive with a buffered guaiac impregnated test paper. There was an apparent overall false positive rate of 25.5% in this study of normal intubated individuals, but even using less than 25 micrograms of hemoglobin / ml. as the test cut-off, 11.8% showed a positive reaction. The positive rate will be affected by the method of collection. A traumatic intubation can be expected to produce some degree of bleeding.

STUDIES HemaPrompt Gastric was studied with

a) 12 patient gastric samples obtained by gastroscopy.
b) 8 healthy volunteer gastric samples obtained by intubation.
c) samples of a synthetic gastric juice of Phosphate Buffered Saline (PBS) each titrated with HCl to give pH's ranging from 1.0 to 7.0 and hemoglobin concentrations of 50, 100, 200 and 500 mcg/ml.

(a) It was found of the patient samples, none were positive initially, 37.5% (3/8) were positive with blood added to produce a concentration of 50 mcg / ml Hb, and 66% (8/12) were positive with 100 mcg / ml Hb and 100% of samples with blood added in concentrations of 200 mcg Hb / ml or greater reacted positively.

(b) Of the intubated volunteer samples, 37.5% (3/8) were positive with no added blood. 60% (3/5) were positive with 20 mcg/ml Hb added, 87.5% *(718)* were positive with 50 mcg/ml Hb added to the specimen, and 100% were positive at concentrations of 100 mcg / ml and greater of added hemoglobin. All samples with blood added in concentrations of 200 mcg Hb / ml or greater reacted positively, and all reacted in less than 60 seconds. The positive rate will be affected by the method of collection. A traumatic intubation can be expected to produce some degree of bleeding and an initial negative result under these circumstances assumes added weight compared to a positive result..

(c) Of the PBS samples, 50 mcg Hb/ ml produced a positive reaction 44% (7/16) of the time, with 100 mcg / ml 81.25% (13/16) of samples showed a positive reaction. At 200 mcg / ml and above [all samples showed a positive reaction. Furthermore, concentrations of ranitidine, ferrous sulfate, and an antacid (Mylanta) to be expected in the stomach after a maximum recommended dosing did not alter the HemaPrompt Gastric results. This does not necessarily apply in overdose situations when excessive iron compounds and certain H2 blockers e.g. cimetidine (Tagamet) could produce false positive reactions, and excess antacid or ranitidine (Zantac) could produce a false negative.

The samples from each person were repeated over a two week period. Results demonstrated excellent HemaPrompt Gastric reproducibility at levels above 100 mcg/ ml gastric juice with all samples stored up to 10 days at 5°C and showed excellent comparison to results obtained on the same samples with another commercially available test for this purpose

It was concluded that with gastric juice, HemaPrompt reacted reliably and definitely to hemoglobin levels above 100mcg / ml. gastric juice.

All monitors reacted in the expected manner (+ve turned blue and the "negative" monitor remained non-reactive). Exposing the guaiac paper to UV light for ten minutes inactivated the expected reaction.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Robert Schreiber, M.D.
Aerscher Diagnostics
353 High Street
Chestertown, Maryland 21620

Re: k031356
Trade/Device Name: HemaPrompt Gastric
Regulation Number: 21 CFR § 864.6550
Regulation Name: Reagent Occult Blood
Regulatory Class: II
Product Code: KHE
Dated: July 29, 2003
Received: July 29,2003

Dear Dr. Schreiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5 10(k) Number (if known): K031356

Device Name: HemaPrompt Gastric

Indications For Use:

HemaPrompt Gastric is a guaiac-based in-vitro method for the qualitative detection of occult blood in gastric aspirate or vomitus by medical professionals only. A separate segment of pH paper is provided on the slide for estimation of pH of the gastric juice

It is used for the early detection of occult blood in such conditions as gastric trauma, gastric or duodenal ulceration, gastric cancer, esophageal varices, situations of exogenous or endogenous gastritis, leukemia, and hereditary telangiectasia. These conditions may be encountered in the emergency room, recovery room or intensive care.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ **OR** **Over-The--Counter Use**____

(Per 21 CFR 801.109)

(Optional Format 1-2-.96)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 031356 /s1